Consumer Medicine Information

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Guide to parts

Things to do before you inject

A. Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, an adhesive bandage and a sharps disposal container (maybe provided).

For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting. Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the new pre-filled syringe and the other supplies.

- DO NOT try to warm the syringe by using a heat source such as hot water or microwave
- DO NOT leave the pre-filled syringe exposed to direct sunlight
- DO NOT shake the pre-filled syringe
- Keep pre-filled syringes out of the sight and reach of children

B. Open the tray, peeling away the cover. Grab the pre-filled syringe safety guard to remove the pre-filled syringe from the tray.

For safety reasons:
- DO NOT grasp the plunger
- DO NOT grasp the grey needle cap

C. Inspect the medicine and pre-filled syringe.

- DO NOT use the pre-filled syringe if:
  - The medicine is cloudy or there are particles in it. It must be a clear and colourless liquid.
  - Any part appears cracked or broken.
  - The grey needle cap is missing or not securely attached.
  - The expiry date printed on the label has passed the last day of the month shown.

In all cases, call your doctor or healthcare provider.

Where to inject

A. Wash hands thoroughly. Prepare and clean your injection site.

You can use:
- Upper part of your thigh
- Belly, except for a 5 cm (2-inch) area right around your belly button
- Outer area of upper arm (only if someone else is giving you the injection)

Clean the injection site with an alcohol wipe. Let your skin dry.
- DO NOT touch the injection site before injecting
- DO NOT inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.

B. Carefully pull the grey needle cap straight out and away from your body.

C. Pinch your injection site to create a firm surface.

- It is important to keep the skin pinched when injecting.

How to inject

A. Hold the pinch. INSERT needle into skin.

- DO NOT touch the cleaned area of the skin

B. PUSH the plunger with slow and constant pressure until you feel or hear a "snap". Push all the way down through the snap.

Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. Keep the syringe and sharps disposal container out of sight and reach of children.

- DO NOT reuse the pre-filled syringe
- DO NOT recycle pre-filled syringes or throw them into household waste

B. Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. DO NOT rub the injection site. Apply an adhesive bandage if needed.

Further information on use

How much to inject

The usual dose is one subcutaneous injection 24 hours after the end of each chemotherapy cycle.
When to inject
Use Tezmota 24 hours after the end of each chemotherapy cycle. Your doctor will tell you when to begin your treatment and when to stop.

If you forget your injection
If you miss your scheduled dose, talk to your doctor, nurse or pharmacist as soon as possible.

If you inject too much (overdose)
If you inject more Tezmota than you need, talk to your doctor, nurse or pharmacist. If you feel unwell in any way you talk to your doctor, nurse or pharmacist immediately.

While you are using it
Things you must do
Watch for any signs or symptoms of infection. There are many ways an infection may show itself. Symptoms of an infection include:
• fever (a temperature of 38.2°C or greater, or as your doctor suggests)
• chills
• rash
• sore throat
• diarrhoea
• earache
• difficult or painful breathing, coughing or wheezing.

Go straight to your hospital if you develop any of these symptoms.
If you are about to be started on any new medicine, tell your doctor, nurse and pharmacist that you are using Tezmota.
Tell any other doctors, dentists and pharmacists who treat you that you are using Tezmota.
Tell your doctor immediately if you become pregnant while taking this medicine.
Tell your doctor immediately if you develop any of these symptoms.
If you are about to be started on any new medicine, tell your doctor, nurse and pharmacist that you are using Tezmota.
Tell any other doctors, dentists and pharmacists who treat you that you are using Tezmota.
Tell your doctor immediately if you become pregnant while taking this medicine.
Tell your doctor immediately if you develop any of these symptoms.

Things you must not do
Do not use Tezmota to treat any other complaints unless your doctor tells you to.
Do not give Tezmota to anyone else, even if they have the same condition as you.

Side effects
Tell your doctor, nurse or pharmacist as soon as possible if you have any problems while using Tezmota, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

All medicines can have side effects. Some side effects may be serious and need medical attention. Other side effects are minor and are likely to be temporary. You may also experience side effects caused by other medicines you are taking at the same time as Tezmota.

Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

• temporary bone pain, such as in the lower back or in the long bones of the arms or legs
This pain is usually relieved with non-prescription painkillers, like paracetamol. If you continue to have bone pain even after having taken this form of pain relief, you should speak to your doctor, as you may need a prescription medicine.
• headache
• general aches and pains in joints and muscles
• reddish or purplish blotches under the skin
• injection site pain and redness of the skin at the injection site.

Tell your doctor immediately if you notice any of the following:

• pain in the upper left side of the stomach (abdomen)
• left shoulder pain
• dizziness
• fever and painful skin lesions most commonly on your arms, legs and sometimes on your face and neck
• blood in the urine
• tiredness, shortness of breath, easy bleeding and frequent infections.
The above list includes serious side effects that may require medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

• swelling or puffiness
• swelling of your stomach-area (abdomen) and feeling of fullness
• general feeling of tiredness.

These may be serious side effects of Tezmota. You may need urgent medical attention.

Serious side effects are rare or uncommon.
If any of the following happen, stop taking Tezmota and go straight to hospital, as you may need urgent medical attention:

• rash over a large area of the body, itching or hives
• shortness of breath, wheezing or difficulty breathing
• coughing up blood, bleeding from the lungs
• swelling of the face, lips, tongue or other parts of the body
• faintness
• rapid pulse or sweating.

These are very serious side effects. If you have them you may have had a serious allergic reaction to Tezmota. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything that worries you or that is making you feel unwell.
Other side effects not listed above may occur in some people.

After using it

Storage
Keep Tezmota in a refrigerator at a temperature of 2°C to 8°C.

Do not freeze.
Do not use Tezmota if you think it has been frozen. Exposure to room temperature of up to 3 days will not harm Tezmota.
Keep your medicine in its pack. Protect it from light.
Keep it where children cannot reach it.

Disposal
Once you have injected Tezmota, do not put the grey needle cap back on the used syringe.
Discard the used syringe into an approved, puncture-resistant sharps container and keep it out of the reach of children.
Never put the used syringes into your normal household rubbish bin.
Dispose of the full puncture-resistant sharps container as instructed by your doctor, nurse or pharmacist.

Product description

What it looks like
Tezmota is a clear, colourless solution. It is supplied in a carton as a pre-filled syringe with an automatic needle guard.

Ingredients
Active ingredient: 6 mg pegfilgrastim (rbe). Inactive ingredients:
• sodium acetate
• sorbitol
• polysorbate 20
• Water for Injections.
The grey needle cap on the pre-filled syringe with an automatic needle guard contains a derivative of latex.
Tezmota does not contain lactose, gluten, tartrazine or any other azo dyes.

Sponsor
Amgen Australia Pty Ltd
ABN 31 051 057 428
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NORTH RYDE NSW 2113
This leaflet was prepared in October 2020.
Australian Registration Number:
Pre-filled syringe with automatic needle guard AUST R 298402
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